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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/881,556	06/14/2001	J. Neil Simonsen	9000-0054	6837

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ROBINS & PASTERNAK LLP
545 MIDDLEFIELD ROAD
SUITE 180
MENLO PARK, CA 94025

EXAMINER	
NAVARRO, ALBERT MARK	
ART UNIT	**PAPER NUMBER**
1645	7

DATE MAILED: 08/07/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/881,556	Simonsen
Examiner	**Art Unit**
Mark Navarro	1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☐ Responsive to communication(s) filed on _____.

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-31* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☐ Claim(s) _____ is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☒ Claims *1-31* are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-2, 4-5, and 7-8, drawn to DNA encoding AG1, classified in class 536, subclass 23.1.

II. Claims 1, 3-4, and 6-8, drawn to DNA encoding AG2, classified in class 536, subclass 23.1.

III. Claims 9-10, 12-13 and 30, drawn to AG1 polypeptides, classified in class 530, subclass 350.

IV. Claims 9, 11-13 and 30, drawn to AG2 polypeptides, classified in class 530, subclass 350.

V. Claims 14-15, 17, 19, and 31, drawn to antibodies to AG1, classified in class 530, subclass 387.1.

VI. Claims 14, 16, 18-19, and 31, drawn to antibodies to AG2, classified in class 530, subclass 387.1.

VII. Claim 20, drawn to methods of treatment comprising administering AG1 polypeptides, classified in class 424, subclass 184.1.

VIII. Claim 20, drawn to methods of treatment comprising administering AG2 polypeptides, classified in class 424, subclass 184.1.

IX. Claim 21, drawn to methods of treatment comprising administering antibodies to AG1, classified in class 424, subclass 130.1.

X. Claim 21, drawn to methods of treatment comprising administering antibodies to AG2, classified in class 424, subclass 184.1.

XI. Claim 22, drawn to methods of producing compositions of AG1, classified in class 435, subclass 68.1.

XII. Claim 22, drawn to methods of producing compositions of AG2, classified in class 435, subclass 68.1.

XIII. Claims 23-24, drawn to methods of producing antibodies to AG1, classified in class 435, subclass 69.6.

XIV. Claims 23 and 25, drawn to methods of producing antibodies to AG2, classified in class 435, subclass 69.6.

XV. Claim 26, drawn to methods of detecting AG1 antibodies, classified in class 435, subclass 7.1.

XVI. Claim 26, drawn to methods of detecting AG2 antibodies, classified in class 435, subclass 7.1.

XVII. Claims 27-28, drawn to methods of detecting AG1, classified in class 435, subclass 7.4.

XVIII. Claims 27 and 29, drawn to methods of detecting AG2, classified in class 435, subclass 7.4.

2. The inventions are distinct, each from the other because of the following reasons:

MPEP 803.04 recites that nucleotide sequences encoding different proteins are structurally distinct chemical compounds and are unrelated to one another. These sequences are thus deemed to normally constitute independent and distinct inventions. In view that AG1 and AG2 each have a separate primary, secondary, and tertiary structure, they are deemed independent and distinct inventions.

Invention I drawn to a DNA molecule, and Invention III drawn to a protein are distinct since they are products with different structure and biological properties. The protein is made of amino acids whereas the nucleic acid molecule consists of nucleotides. Further methods known in the art used to make the polypeptide require different reagents and parameters from the methods of making nucleic acid encoding the protein and the method of making the polypeptide does not require the nucleic acid. For instance, the protein can be made by Merrifield chemical synthesis or affinity chromatography.

Invention V drawn to an antibody is distinct from Inventions I-IV and VI-XVIII, since it has an inherent affinity, avidity, and specificity that DNA or a simple protein is not capable of expressing.

Invention VII, drawn to methods of treatment and Invention III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different

process of using that product (MPEP § 806.05(h)). In the instant case the polypeptide may be administered in vivo as claimed, or alternatively may be incorporated into an in vitro assay to screen for the presence of antibodies.

Invention IX, drawn to methods of treatment with antibodies and Invention V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antibodies may be administered in vivo as claimed, or alternatively may be incorporated into an in vitro assay to screen for the presence of the antigen.

Inventions XI, drawn to methods of producing a composition and Invention III are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the composition can be produced recombinantly as claimed, or alternatively may be synthesized enzymatically.

Invention XIII, drawn to methods of producing antibodies is distinct from Inventions I-XII and XIV-XVIII, since it requires additional biological reagents and parameters for producing the antibody.

Invention XV, drawn to methods of detecting antibodies is distinct from Inventions I-XIV and XVI-XVIII, since it requires additional biological reagents and parameters for detecting the antibody.

Invention XVII, drawn to methods of detecting antigens is distinct from Inventions I-XVIII, since it requires additional biological reagents and parameters for detecting the antigen of interest.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their separate classification and their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Navarro whose telephone number is (703) 306-3225.

Mark Navarro

Primary Examiner

August 6, 2002